510(k) Summary – K123990

APR 26 2013

Submitter:

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Date Prepared: December 21, 2012

Device Trade Name: Sentrant Introducer Sheath with Hydrophilic Coating

Device Classification: Class II

Classification Name: Catheter Introducer

Regulation Number: 21 CFR 870.1340

Classification Product Code: DYB

Classification Panel: Cardiovascular

Predicate Devices: Cook Extra Large Check-Flo® Introducer (K902469)
GORE Dry Seal Sheath (K093791)

Device Description:
The Sentrant Sheath is a single-use, disposable, hydrophilic-coated catheter designed to provide a flexible and hemostatic conduit for the insertion of endovascular devices and to minimize blood loss associated with vascular procedures. The system is comprised of a dilator and an introducer sheath. The system accommodates a 0.035 in (0.89 mm) guidewire and is available in 28 and 64 cm lengths and in sizes from 12 to 26 Fr in 2 French increments.

The dilator is radiopaque and has a tapered, flexible tip that facilitates atraumatic tracking through the vasculature. A female luer taper fitting is located on the distal end of the dilator grip. The proximal end of the dilator grip is threaded to allow the dilator to be secured to the sheath seal housing.

The introducer sheath is comprised of a hydrophilic, coil-reinforced catheter that is attached to a rigid seal housing containing the hemostatic valve assembly. A sideport extension with a 3-way valve is attached to the seal housing. A radiopaque markerband is located at the distal tip of the sheath. The device also has a suture loop for attaching it to the patient and a strain relief to minimize kinking of the catheter where it joins to the seal housing.

Statement of Intended Use:
The Sentrant Introducer Sheath with Hydrophilic Coating is intended to provide a conduit for the insertion of diagnostic or endovascular devices into the vasculature and minimize blood loss associated with such insertions.

Substantial Equivalence:
The documentation provided includes mechanical test results that demonstrate the Sentrant Sheath is substantially equivalent to the Cook Extra Large Check-Flo Introducer (K902469) and the GORE Dry Seal Sheath (K093791).

Bench Testing Performance Data:
The Sentrant Sheath was tested through a series of physical, mechanical and bench tests, listed below, to evaluate its performance and verify that it meets the required performance specifications. All of the predetermined acceptance criteria were met and results passed.

- OD of Sheath Tubing
- OD of Dilator
- Sheath Working Length
- Dilator Working Length
- Hydrophilic Coating Length
- Guidewire Acceptance
- Grip to Dilator Tensile Strength
- Seal Housing to Sheath Tubing Tensile Test
- Seal Cap to Seal Housing Tensile Strength
- Atraumatic Tip (A-Tip) Lamination Tensile Strength
- Sideport Torque Test
- Leak Test
- Kink Test
- Test for Liquid Leakage Under Pressure

Biocompatibility Testing:

The following Biocompatibility testing was performed on the Sentrant Sheath per the requirements of ISO10993-1. All of the predetermined acceptance criteria were met and results passed.

- ISO MEM Elution, Cytotoxicity
- ISO Maximization Sensitization
- ISO Intracutaneous Reactivity
- ISO Acute Systemic Toxicity
- USP Material Mediated Pyrogen
- ASTM In-vitro Hemolysis
- Complement Activation C3a and SC5b-9
- ASTM Partial Thromboplastin Time
- In-vivo Thromboresistance
- Inductively Coupled Plasma Spectroscopy

Conclusion:

The Sentrant Introducer Sheath is substantially equivalent in intended use, technological characteristics and performance of the predicate introducer catheters, the Cook Extra Large Check-Flo® Introducer (K902469) and the GORE DrySeal Sheath (K093791).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 26, 2013

Medtronic Vascular
C/O Kelley Lamke, Regulatory Affairs Specialist
3576 Unocal Place
Santa Rosa, CA 95403

Re: K123990
Trade/Device Name: Sentrant Introducer Sheath with Hydrophilic Coating
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: March 12, 2013
Received: March 13, 2013

Dear Ms. Kelley Lamke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K123990

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Indications for Use:

The Sentrant Introducer Sheath with Hydrophilic Coating is intended to provide a conduit for the insertion of diagnostic or endovascular devices into the vasculature and minimize blood loss associated with such insertions.

Prescription Use **X**	AND/OR	Over-The-Counter Use ___
(21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner